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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/716,473	11/20/2003	Yoshiya Gunji	US-104	5759
38108	7590	07/31/2006	EXAMINER	
CERMAK & KENEALY LLP ACS LLC 515 EAST BRADDOCK ROAD SUITE B ALEXANDRIA, VA 22314			ROBINSON, HOPE A	
			ART UNIT	PAPER NUMBER
			1656	

DATE MAILED: 07/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/716,473	Applicant(s) GUNJI ET AL.	
	Examiner Hope A. Robinson	Art Unit 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _____ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 May 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-2 and 4-8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2 and 4-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Application Status

1. Applicant's response to the Office Action mailed January 12, 2006 on June 11, 2006 is acknowledged. It is noted that applicant filed a substitute specification, however, this was not entered because the marked up copy has no markings to indicate modifications made.

Claim Disposition

2. Claims 7-8 have been added. Claim 3 has been cancelled. Claims 1-2, and 4-8 are pending and are under examination.

Maintained-Specification Objection

3. The specification remains objected to because of the following informalities:

The specification remains objected to as the priority information is not recorded on page 1 of the specification, for example, "This application claims benefit under 35 U.S.C. 119(a-d) to Application Number 2002-336346, filed November 20, 2002 in Japan.

Correction is required.

Withdrawn-Claim Rejections - 35 USC § 112

4. Previous rejection to claims under 35 U.S.C. 112, first and second paragraphs, are withdrawn by virtue of amendments submitted.

Withdrawn-Claim Rejections - 35 USC § 102

5. Previous rejection to claims under 35 U.S.C. 102 is withdrawn by virtue of amendments submitted.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-2 and 4-8 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claimed invention is directed to a method of producing L-amino acids from a *Methylophilus* bacterium, following mutations of the host cell. The claim recites that there's an increase in copy number of a gene coding for 2-keto-3-deoxy-6-phosphogluconate aldolase or modifying an expression regulatory sequence which reads on a mutation or simply substituting one promoter for another. There is no indicia in the claims as to how the "increased in copy number" is obtained. While it is acknowledged that the claims are not drawn to increasing the copy number and are instead drawn to method of producing an L-amino acid, MPEP 2163 states

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"[t]he claimed invention as a whole may not be adequately described if the claims require an essential or critical feature which is not adequately described in the specification and which is not conventional in the art or known to one of ordinary skill in the art". In this case the method is directed to producing L-amino acid comprising culturing a microorganism described as being a methanol-utilizing bacterium with a modified pathway, said to be enhanced compared to the wild type. In defining how the enhancement is achieved the relative terminology, "increase copy number" is utilized and the relative term "modifying an expression regulatory sequence". The claims do not set forth how either process is achieved which is critical to the modifications in the bacterium that is enhanced for producing L-amino acid in the medium in excess. Thus, for all these reasons the specification lacks adequate written description.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

7. Claim 1-2 and 4-8 are rejected under 35 U.S.C. 112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 and the dependent claims hereto are indefinite for the recitation of "increasing copy number and modifying an expression regulatory sequence" as these phrases are relative. It is suggested that a reference point is provided in the claim, for example, "increase copy number of a gene compared to the wild-type" and indication of whether modifying an expression

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regulatory sequence, means addition of a promoter or mutagenesis. The dependent claims hereto are also included as they do not rectify the deficiency.

Response to Arguments

8. The response filed on June 11, 2006 has been considered. Note that the rejections of record have been withdrawn. Note also that the specification remains objected to with regard to the priority information as the amendment filed did not address the issue and the newly submitted specification did not show this amendment. In addition, a new ground of rejection has been instituted under 35 U.S.C. 112, first and second paragraph for the reasons stated above.

Conclusion


9. No claims are presently allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope A. Robinson whose telephone number is 571-272-0957. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr, can be reached at (571) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Hope Robinson, MS 

Patent Examiner

7/24/06

**HOPE ROBINSON
PATENT EXAMINER**